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Indian Standard

SPECIFICATION FOR RUBBER TUBING FOR MEDICAL USE

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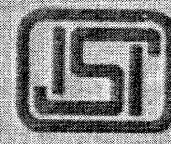

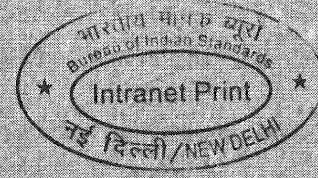

INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

January 1971

Indian Standard

SPECIFICATION FOR RUBBER TUBING FOR MEDICAL USE

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0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 15 December 1969, after the draft finalized by the Rubber Products Sectional Committee had been approved by the Chemical Division Council.

0.2 The Rubber Products Sectional Committee, at the time of revising IS : 637-1955* felt the need for a separate specification for tubings meant for medical use since in the manufacture of these tubings extreme caution is to be exercised to avoid all toxic elements and harmful ingredients. The present standard does not include transfusion tubings and stethoscopic tubings.

0.3 At present most of the rubber laboratories in this country have no facilities to carry out test for toxicity and test for detecting inhibitory substances in the rubber tubings. However, where facilities are available methods given in Appendix A and Appendix B may be followed.

0.4 In the preparation of this standard considerable assistance has been derived from B.S. 1882-1966 'Flexible tubing for medical use', issued by the British Standards Institution.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960†. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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1. SCOPE

1.1 This standard prescribes the requirements, methods of sampling and test for rubber tubings for medical use.

2. TERMINOLOGY

2.1 Anti-Static — Having a resistance of over 5×10^4 ohms and less than 10^8 ohms.

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*Specification for plain rubber tubings. (Since revised).

†Rules for rounding off numerical values. (*revised*).

3. TYPES

3.1 This standard covers the following four types of rubber tubings:

Type 1 — pressure tubing

Type 2 — drainage tubing

Type 3 — Paul's tubing

Type 4 — antistatic tubing

4. REQUIREMENTS

4.1 General

4.1.1 The rubber tubing shall be made of natural or synthetic rubber or combination of both, compounded and vulcanized to meet all the requirements of this specification.

4.1.2 The rubber tubing shall not contain any reclaim rubber or vulcanized waste.

4.1.3 Type 3 tubing may be made from rubber latex or calendered rubber sheets.

4.1.4 The rubber tubings (except for Type 3) shall be uniformly circular and concentric in section. All tubings shall be non-porous, of homogeneous character throughout and free from grit, pitting, loose dusting agents, blooming and other visible defects.

4.2 Dimensions

4.2.1 *Nominal Diameter and Thickness* — The dimensions for the rubber tubings shall be as given in Tables 1, 2 and 3 for Types 1, 2, 3 and 4 tubings.

4.2.2 *Length* — Unless otherwise specified the tubing shall be supplied in coils of not less than 10 m lengths.

4.3 Physical Requirements — Physical requirements of rubber used for different types of tubings shall be as given in Table 4.

4.3.1 After ageing at 70 ± 1°C for a period of 168 hours as specified in **7.3.2**, the change in tensile strength and elongation at break shall not vary by more than $^{+10}_{-25}$ percent of the corresponding values obtained before ageing.

4.3.2 After heat sterilization test as specified in **7.3.3**, the change in tensile strength and elongation at break shall not vary by more than $^{+10}_{-25}$ percent of the corresponding values obtained before heat sterilization.

TABLE 1 INTERNAL DIAMETER AND WALL THICKNESS OF TYPE 1 AND TYPE 4 TUBINGS

(*Clause* 4.2.1)

All dimensions in millimetres.

Sl No.	Internal Diameter		Wall Thickness			
			Thin Wall		Thick Wall	
	Nominal	Tolerance	Nominal	Tolerance	Nominal	Tolerance
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	3·0	± 0·3	—	—	3·00	± 0·30
ii)	5·0	± 0·4	3·50	± 0·35	5·00	± 0·40
iii)	6·5	± 0·4	4·00	± 0·40	6·50	± 0·40
iv)	8·0	± 0·4	5·50	± 0·40	—	—
v)	9·5	± 0·4	6·50	± 0·40	—	—

TABLE 2 INTERNAL DIAMETER AND WALL THICKNESS OF TYPE 2 TUBING

(*Clause* 4.2.1)

All dimensions in millimetres.

Sl No.	Nominal Internal Diameter With Tolerance	Wall Thickness With Tolerance
(1)	(2)	(3)
i)	1·25 ± 0·20	0·60 ± 0·15
ii)	1·50 ± 0·20	0·70 ± 0·15
iii)	2·50 ± 0·20	0·85 ± 0·15
iv)	3·00 ± 0·30	1·00 ± 0·20
v)	4·00 ± 0·30	1·20 ± 0·20
vi)	5·00 ± 0·30	1·40 ± 0·20
vii)	6·30 ± 0·40	1·70 ± 0·20
viii)	8·00 ± 0·40	2·00 ± 0·20
ix)	9·00 ± 0·40	2·30 ± 0·20
x)	10·00 ± 0·40	2·50 ± 0·20
xi)	11·00 ± 0·40	2·80 ± 0·20
xii)	12·50 ± 0·50	3·20 ± 0·30

TABLE 3 OUTSIDE WIDTH AND WALL THICKNESS OF TYPE 3 TUBING

(*Clause* 4.2.1)

All dimensions in millimetres.

Sl No.	Outside Width of Flat Tubes (Nominal Width With Tolerance)	Wall Thickness (Nominal Thickness With Tolerance)
(1)	(2)	(3)
i)	6·50 ± 0·50	0·4 ± 0·1
ii)	9·50 ± 0·50	0·4 ± 0·1
iii)	12·50 ± 0·75	0·4 ± 0·1
iv)	19·00 ± 0·75	0·4 ± 0·1
v)	25·00 ± 0·75	0·4 ± 0·1
vi)	32·00 ± 0·75	0·4 ± 0·1
vii)	38·00 ± 0·75	0·4 ± 0·1
viii)	50·00 ± 1·00	0·4 ± 0·1

TABLE 4 PHYSICAL REQUIREMENTS OF RUBBER, USED FOR TUBINGS

(*Clause* 4.3)

Type	Before Ageing	
	Tensile Strength, *Min*	Elongation at Break, *Min*
(1)	(2)	(3)
	kgf/cm²	percent
Type 1	105	400
Type 2	105	500
Type 3	105	600
Type 4	140	400

4.4 The tubings shall be free from harmful contaminations of heavy metals, arsenic, copper, iron and manganese.

4.4.1 The concentration of each of the metallic impurities in **4.4** shall not exceed 5 ppm in the sterile pyrogen-free isotonic saline solution prescribed in **7.4.1.**

4.4.2 *Electrical Requirements* — Type 4 tubing in addition to the requirements prescribed in **4.1.1** to **4.4.1**, shall comply with the following electrical requirements:

Nature of Tubing	*Electrical Resistance, Ohms*	
	Min	*Max*
Anaesthetic tubing which constitutes the main part of any connection between the anaesthetic apparatus and the patient	5×10^4 per 1·5 m	10^7 per 1·5 m
Tubing other than the foregoing	—	10^8 per 1·5 m

5. MARKING AND PACKING

5.1 Marking — Each length of the tubing shall be plainly and indelibly marked adjacent to each and with:

a) the internal diameter of the tube;

b) the manufacturer's name or trade-mark, if any or both;

c) the month and year of manufacture, if specified by the purchaser; and

d) the type of tubing.

5.1.1 Antistatic Tubing, Type 4, shall be marked with a continuous in lemon yellow colour line.

5.1.2 The tubing may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

5.2 Packing — The material may be packed and marked (*see* **5.1**) as agreed to between the purchaser and the supplier.

6. SAMPLING AND CRITERIA FOR CONFORMITY

6.1 Sampling — Representative samples for various tests shall be drawn according to the method and scale of sampling given in Appendix C.

7. TEST METHODS

7.1 Unless otherwise agreed to between the purchaser and the supplier, all tests shall be carried out within three months of the date of receipt of the material by the purchaser.

7.2 Test Pieces — As the tubing is not in a form which is suitable for carrying out physical tests, the tests on Types 1, 2 and 4 shall be carried out on press cured slabs made from the same mix and vulcanized as closely as possible to the same degree as the tubing. For Type 3 tubing the test pieces shall be cut from the flat tubing in the sizes 12·5 mm and upwards. For sizes 6·4 mm and 9·5 mm test sheets shall be prepared from similar materials as for the tubing and shall be vulcanized under similar conditions.

7.3 Physical Properties

7.3.1 *Tensile Strength and Elongation at Break* — Carry out the test on dumb-bell test pieces cut out of the article or press cured slab (**7.2**), in accordance with the method prescribed in IS : 3400 (Part I)-1965*.

7.3.2 *Accelerated Ageing* — Subject dumb-bell test pieces as in **7.3.1** to ageing at 70°±1°C for 168 h in an air oven or a cell oven in accordance with the method prescribed in IS : 3400 (Part IV)-1965† and test according to **7.3.1.**

7.3.3 *Heat Sterilization Test* — Loosely wrap dumb-bell test pieces prepared for mechanical tests in surgical gauze in such a manner that all rubber surfaces are separated from one another, and subject to heat-treatment at $134^{\circ}\ ^{+4}_{-0}$ °C for 3 minutes in a pressure steam sterilizer. On the completion of the test period release the steam pressure. Take out the rubber test pieces from the gauze and allow to cool to normal room temperature as quickly as possible. Repeat the process after a lapse of at least 20 minutes but as soon as possible thereafter until three heatings have been made. After completion of the heat treatment, allow the test pieces to cool at room temperature for 24 h and then test for tensile strength and elongation at break as in **7.3.1.**

7.4 Test for Metallic Contaminations in the Tubing

7.4.1 *Preparation of Test Solution* — Pass 40 ml portions of sterile pyrogen free isotonic saline solution containing nine grams of sodium chloride per litre at room temperature through a metre-length tubing at a flow rate of approximately 10 ml per minute and collect the effluent. Make up the solution to 250 ml.

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*Methods of test for vulcanized rubbers: Part I Tensile stress-strain properties.

†Methods of test for vulcanized rubbers: Part IV Accelerated ageing.

7.4.2 *Test for Arsenic* — Carry out the test for arsenic as prescribed in IS : 2088-1962* with 10 ml of the solution, using for comparison a stain obtained with 0·005 mg of arsenic trioxide (As_2O_3).

7.4.3 *Test for Copper, Manganese and Iron* — Carry out test for copper, manganese and iron as prescribed in NR : 4, NR : 5 and NR : 6 of IS : 3600 (Part I)-1966† respectively with test solutions, prepared according to **7.4.1.**

7.4.4 *Test for Heavy Metal* — Heavy metal contamination shall be tested in accordance with the method given in Appendix D.

7.4.5 *Test for Electrical Properties* — The Type 4 tubings shall be tested as prescribed in Appendix E.

APPENDIX A

(*Clause* 0.3)

TEST FOR TOXICITY

A-1. PROCEDURE

A-1.1 Fill a 150 mm length of tubing as completely as practicable with sterile pyrogen-free isotonic saline solution containing 9 g of sodium chloride per litre, clamp the ends securely to retain the solution and immerse the filled set completely in water. Heat the water and maintain at not less than 85°C for 1 hour. Drain the contents of the tubing. Inject intravenously 0·5 ml of the solution so prepared into each of five healthy mice weighing 20±3 g. At the end of 4, 24 and 48 h examine the animals for discernible symptoms of toxicity If any of the animals show gross signs of toxicity or die, repeat the test with five unused mice weighing 20±3 g each.

A-1.1.1 The test shall be deemed to be satisfied if all the animals survive for 48 h.

APPENDIX B

(*Clause* 0.3)

TEST FOR INHIBITORY SUBSTANCES IN RUBBER

B-1. PROCEDURE

B-1.1 Heavily inoculate a blood-agar plate over the entire surface with a young broth culture of *streptococcus pyogens.* The blood-agar plate shall

*Modified Gutzeit method of test for arsenic. (Since revised).
†Methods of test for natural rubber: Part I. (Since revised).

consist of nutrient agar containing 10 percent of horse blood in a Petri dish. Select 5 mm length of representative sample of the tubing. Wash the tubing sample in distilled water, then sterilize them by autoclaving in distilled water for 30 minutes at 120°C. Rinse twice in sterile distilled water and dry. Place the samples on the blood-agar surface applying slight pressure observing the usual asceptic precautions with a minimum distance of 20 mm between each item. Incubate the whole at 37°C for 24 to 48 h. In the absence of inhibitory substances, the growth of *streptococcus pyogens* right to the edge of the sample, is evidenced by haemolysis of the red blood cells. In the presence of inhibitory substances, there is a ring of unhaemolysed blood without bacterial growth around the sample.

APPENDIX C

(*Clause* 6.1)

SAMPLING OF RUBBER TUBING AND CRITERIA FOR CONFORMITY

C-1. SCALE OF SAMPLING

C-1.1 Lot — In any consignment, all the tubings of the same type and manufactured by the same firm under similar conditions of manufacture shall be separated in groups of 5 000 tubings or less and each shall constitute a lot.

C-1.2 Test for the determination of the comformity of the lot to the requirements of this specification shall be carried out for each lot separately. The number of tubings to be selected for carrying out the test for visual and dimensional characteristics shall be in accordance with cols 1 and 2 of Table 5.

TABLE 5 SCALE OF SAMPLING

Lot Size	Number of Tubings to be Selected	Permissible Number of Defective Tubings	Number of Tubings to be Selected for Destructive Type of Characteristic
N	*n*		
(1)	(2)	(3)	(4)
Up to 500	10	0	2
501 „ 1 000	15	1	3
1 001 „ 3 000	30	1	4
3 001 „ 5 000	50	2	5

C-1.3 These tubings shall be selected at random from the lot. In order to ensure the randomness of selection, a random number table as agreed to between the purchaser and the supplier shall be used (*see* IS : 4905-1968*). In case such a table is not available the following procedure shall be adopted:

Starting from any tubing in the lot, count them as 1, 2, 3, ..., up to r and so on in one order, where r is the integral part of N/n (*see* **C-1.2**). Every rth tubing thus counted shall be withdrawn to give the sample for test.

C-2. TEST FOR DIMENSIONAL CHARACTERISTICS

C-2.1 Each of the tubings selected according to **C-1.2** shall be tested for all the dimensions and visual characteristics specified under **4.1** and **4.2**. Any tubing failing to satisfy any of the requirements for dimensional and visual characteristics shall be considered as defective.

C-2.1.1 If the number of defective tubings found in the sample is not more than the corresponding number of permissible defectives given in col 3 of Table 3, the lot shall be declared as conforming to the visual and dimensional requirements. Only such lot shall be further examined for the destructive type of characteristics as given in **C-3**.

C-3. TEST FOR DESTRUCTIVE TYPE OF CHARACTERISTICS

C-3.1 The number of tests for each of the requirements given under **4.3**, **4.4** and **4.5** shall be in accordance with col 1 and 4 of Table 5. For this purpose an equal number of tubings shall first be selected from those already selected according to cols 1 and 2 of Table 5 and found satisfactory in **C-2.1.1**. From each of the selected tubings one test piece shall be taken out for each of these requirements. In case, it is not possible to get the test pieces of required size from the tubing, for testing the requirements under **4.3**, **4.4** and **4.5**, the test shall be carried out on the test piece cut out from test slab (*see* **7.2**). At least two tests shall be carried out for each of these requirements.

C-3.1.1 The lot shall be considered satisfactory for these characteristics if all the test pieces satisfy the relevant specification.

C-4. CRITERIA FOR CONFORMITY

C-4.1 A lot shall be considered to satisfy all the requirements of this specification if it is found satisfactory in **C-2.1.1** and **C-3.1.1**, otherwise not.

*Methods for random sampling.

APPENDIX D

(*Clause* 7.4.4)

TEST FOR HEAVY METALS

D-0. OUTLINE OF THE METHOD

D-0.1 The solution is prepared as in **7.4.1** and tested with aqueous hydrogen sulphide solution. The resultant brown colour if any, is matched with that produced with a standard lead solution.

D-1. APPARATUS

D-1.1 Nessler Tubes — 100 ml capacity.

D-2. REAGENTS

D-2.1 Citric Acid

D-2.2 Concentrated Nitric Acid

D-2.3 Bromophenol Blue Indicator — Dissolve 0·1 g of bromophenol blue in 100 ml of rectified spirit (conforming to IS : 323-1959*).

D-2.4 Copper Sulphate

D-2.5 Hydrogen Sulphide Gas — from Kipp's apparatus.

D-2.6 Dilute Nitric Acid — approximately 1 percent.

D-2.7 Ammonium Hydroxide — Dilute 1 volume of liquid ammonia (sp gr 0·92) with 10 volumes of water.

D-2.8 Thymol Blue Indicator — Dissolve 0·1 g of thymol blue in 100 ml of rectified spirit (conforming to IS : 323-1959*).

D-2.9 Potassium Cyanide Solution — 10 percent (*w/v*).

D-2.10 Hydrogen Sulphide Solution — freshly prepared saturated solution.

D-2.11 Standard Lead Solution — Dissolve 0·800 g of lead nitrate in water and make up the solution to exactly 1 000 ml. Pipette out 10 ml of the solution and dilute it again with water to 1 000 ml. One millilitre of the final solution contains 0·005 mg of lead (Pb). The solution shall be freshly prepared.

*Specification for rectified spirit (*revised*).

D-3. PROCEDURE

D-3.1 Prepare a solution as in **7.4.1** but make up the volume to 100 ml. Transfer the solution to a beaker. Add 5 g of citric acid and adjust *p*H 3·0 to 3·4 by adding ammonium hydroxide to give a yellow purple colour with bromophenol blue indicator. Add about 5 g of copper sulphate to act as co-precipitant. Precipitate sulphides by passing hydrogen sulphide until solution is saturated. Dissolve the sulphides, without previous washing, with 5 ml of hot dilute nitric acid, drawing solution through filter into the original flask; wash with hot water, and collect the washing along with the solution in nitric acid. Boil to remove sulphuretted hydrogen. Concentrate the content to about 75 ml. Add 3 g to 4 ml of concentrated nitric acid previously dissolved in water, make ammoniacal to bring *p*H between 8·5 and 10 (bluish-green to blue towards drop of thymol blue indicator) and add 5 ml of potassium cyanide solution. Transfer to a Nessler tube, add 10 ml of hydrogen sulphide solution, dilute to the mark and shake. Carry out a control test using 1 ml of standard lead solution and the same quantities of other reagents as used in test with the material.

D-3.2 The test solution shall be taken as not having exceeded the limit prescribed if the intensity of colour produced in the test with the material is not greater than that produced in the control test.

APPENDIX E

(Clause 7.4.5)

METHOD OF TEST FOR DETERMINING THE ELECTRICAL RESISTANCE OF TYPE 4 TUBINGS

E-1. OUTLINE OF THE METHOD

E-1.1 The test is carried out on the tubing using a defined system of electrodes by a system suited to factory inspection or service testing.

E-2. APPARATUS

E-2.1 Testing Instruments — For resistances below 10^7 ohms, the test should be carried out preferably with an insulation tester having a nominal open circuit voltage of 500 V dc or with any suitable instrument known to give comparable results. For resistance above 10^7 ohms, electronic, electrostatic, or other suitable test instruments, should be used. The instrument should be sufficiently accurate to determine the resistance with 5 percent and shall not dissipate more than

3 watts in the specimen. The insulation tester has an inherent characteristic that the voltage which it applies to the test piece decreases below its open circuit voltage at low resistance values of the test piece. This is a useful characteristic as it reduces the risk of shock and also of overheating the test piece. Insulation testers of this type can be manually or power driven generators or can be battery or main operated multi-range instruments with similar characteristics. The resistance values obtained will vary with the applied voltage and errors may occur when low test voltages are involved. In cases of dispute, the voltage applied to the test piece should not be less than 40 volts.

E-2.2 Electrodes and Contacts — Electrodes shall be formed on the surface by means of a conductive silver lacquers or a conductive liquid. The conductive liquid shall consist of:

Anhydrous polyethylene glycol of mol. wt. 600	800 parts
Water	200 parts
Wetting agent	1 part
Potassium chloride	10 parts

When a conductive liquid is used, the electrodes contact area shall be completely wetted and remain so until the end of the test. The conductive silver lacquer or colloidal graphite shall be of a type which dries in air at room temperature and the resistance of the dried film should be below 10 ohms/cm^2.

E-3. PREPARATION OF THE TUBING FOR TEST

E-3.1 Conditioning — The article shall be maintained in the undeformed state at a temperature between 15°C and 30°C for a period of not less than 24 h. The article shall then be stored for not less than two hours at a temperature of 27 $\pm$ 2°C in air with a relative humidity of less than 70 percent.

E-3.2 The surfaces which are to be used in the test should be clean. If they have to be cleaned, organic materials which attack or swell the rubber shall not be used neither shall the surface be buffed or abraded.

E-4. TEST PROCEDURE

E-4.1 Immediately after the preparation of the article for test in accordance with **E-3**, apply electrodes and metal contacts as specified in **E-2.2**. Clean metal contacts shall be applied to the treated areas so that the contact area is approximately the same size as but not greater than the treated area. The surface of the product shall not be deformed either during the application of the contacts or during the test and the product shall be supported on an insulating surface except when specified.

Then keep it at a temperature of 15 to 30°C at a relative humidity of less than 70 percent, and carry out the resistance test as specified in **E-4.1.1** or **E-4.1.2** after a period of not less than 15 minutes or more than two hours. Take the resistance reading at 5 ± 1 seconds after the voltage has been applied.

E-4.1.1 Measure the resistance between the metal parts.

E-4.1.2 Carry out two tests as follows:

a) Apply electrodes on the inside surface at one end of the tube and on the outside surface at the other end. The treated areas should be in 25 mm bands around the circumference. Apply the metal contacts to the treated areas and measure the resistance.

b) As in (a) with the coating solution on the other inside and outside surfaces.

NOTE — Care should be taken that the tubing is insulated from any leakage path in parallel to the length under test and that no contact takes place between successive coils along the length of the tubing.

E-5. REPORT

E-5.1 Report the following:

a) Average resistance in ohms,

b) Method of test used (**E-4.1.1** or **E-4.1.2**), and

c) The value of each individual result.

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Dye intermediates
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Explosive and pyrotechnic materials
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Industrial gases
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Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002

Telephone : 27 01 31 (20 lines) **Telegrams : Manaksanstha**

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Regional Offices:		
Western : Novelty Chambers, Grant Road	BOMBAY 400007	37 97 29
Eastern : 5 Chowringhee Approach	CALCUTTA 700072	23-08 02
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117/418 B Sarvodaya Nagar	KANPUR 208005	82 72
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